(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
17 May 2001 (17.05.2001)

PCT

(10) International Publication Number
WO 01/34243 A1

(51) International Patent Classification[7]: A61N 1/37, G01R 31/36

(21) International Application Number: PCT/SE00/01957

(22) International Filing Date: 10 October 2000 (10.10.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9904087-5 11 November 1999 (11.11.1999) SE

(71) Applicant *(for all designated States except US)*: ST. JUDE MEDICAL AB [SE/SE]; S-175 84 Järfälla (SE).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: GUSTAVSSON, Mikael [SE/SE]; Tulegatan 54, S-172 72 Sundbyberg (SE).

(74) Common Representative: ST. JUDE MEDICAL AB; Patent Department, S-175 84 Järfälla (SE).

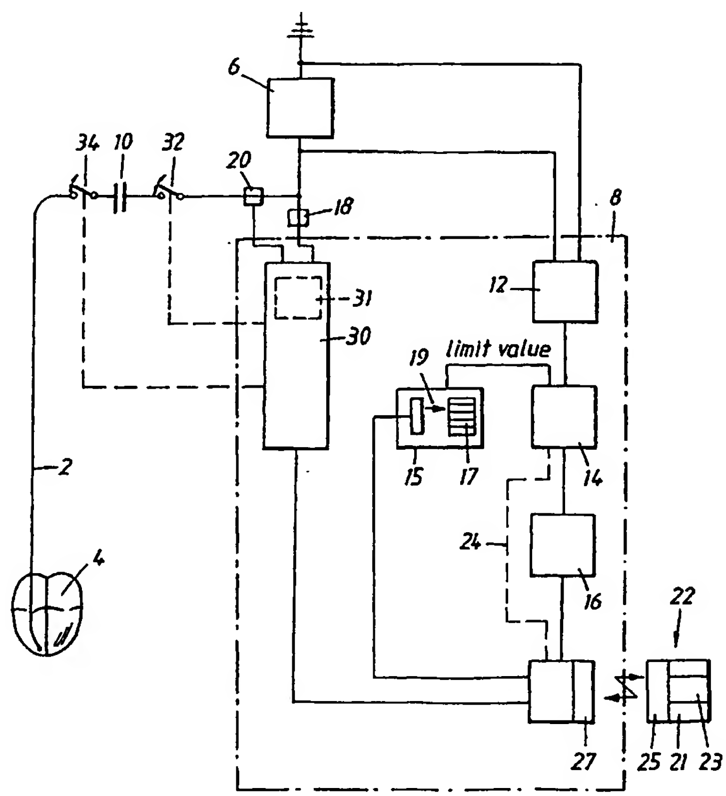
(81) Designated State *(national)*: US.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: RECOMMENDED REPLACEMENT TIME OF AN IMPLANTABLE MEDICAL DEVICE



(57) Abstract: A method of determining recommended replacement time, RRT, of a battery of an implantable medical device comprises the steps of measuring the battery's internal impedance, comparing the measured impedane with a predetermined limit value and determining RRT from the result of this comparison. The limit value is hanged in response to hanges of operating conditions affecting the current consumption of the medical device. A circuit for determining RRT of an implantable heart stimulator having a battery includes an impedane measurement means (12) for measuring the internal impedance of the stimulation battery (6), a comparator means (14) for comparing the measured internal impedance with a predetermined limit value, and a determining means (16, 23) for determining RRT from the result of this comparison. A limit value hanging means (15) is provided to automatically change the limit value of the comparator means in response to changes of operating conditions affecting the current consumption of the heart stimulator.

WO 01/34243 A1

RECOMMENDED REPLACEMENT TIME OF AN IMPLANTABLE MEDICAL DEVICE

Technical Field

The present invention relates to a method and a circuit for determining recommended replacement time, RRT, of a battery of an implantable medical device. The method comprises the steps of measuring the battery's internal impedance, comparing said measured impedance with a predetermined limit value, and determining RRT from the result of this comparison. The circuit includes an impedance measurement means for measuring the internal impedance of the stimulator battery, a comparator means for comparing the measured internal impedance with the predetermined limit value, and a determining means for determining RRT from the result of this comparison.

Background Art

It is of utmost importance to get reliable information about the status of batteries used in implantable medical devices, like heart stimulators, and in particular information about the remaining capacity or remaining charge of the battery. From this information remaining operation time of the device can be determined and this enables the physician to plan for replacement of the battery and/or the medical device at an appropriate time. Several techniques have therefore been proposed for monitoring battery depletion and determining remaining battery capacity.

One of the most commonly used methods consists in monitoring the internal impedance of the battery. US-A-5,620,474 discloses a method to calculate the RRT impedance depending on the operating conditions seen by the pacemaker.The disclosed method in US-A-5,620,474 calculates a new value of the RRT-impedance to be used in the future each time the operating conditions are changed.

Further, US-A-5,800,472 describes determination of recommended replacement time, RRT, of an implantable multimode rate responsive pacemaker by monitoring the battery voltage.

To obtain a more reliable determination of the battery status it has been proposed to independently monitor or measure at least two different parameters indicating the battery depletion. Thus, to reject especially transients in the demand on the battery as criteria for an elective replacement indication, US-A-5,370,668 discloses an implantable medical device in which internal battery impedance measurements are combined with periodical assessments of the loaded terminal voltage of the battery to obtain an elective replacement indication. Another example of such a technique is described in US-A-5,741,307. This publication discloses a method of determining RRT for an implantable cardioverter-defibrillator by measuring battery terminal voltage and capacitor charging time.

From a theoretical point of view the ideal way of determining the remaining capacity of a battery would be measurement of the charge drawn from the battery. Such techniques are proposed in e.g. US-A-4,715,381 and US-A-5,769,873.

As mentioned above, one of the most commonly used methods for determining remaining capacity of the battery of an implanted medical device consists in measurement of the internal impedance of the battery. This impedance increases exponentially with the charge drawn from the battery. Thus, during depletion of the first 50% of the total charge of the battery the change in its impedance can hardly be measured, whereas during depletion of the subsequent 50% of the charge the impedance change will be more and more pronounced.

From information about when a predetermined limit value of the battery internal impedance is reached it is possible to determine how much current is consumed in the actual mode of operation of the device, and it is then also possible to

determine for how long time the remaining charge of the battery will suffice. A recommended replacement time, RRT, for the battery of the medical device or for the medical device, can consequently be determined. As a safety measure RRT is in practice selected 3-6 months before the calculated end of life of the battery.

The current consumption is, however, depending on several factors, such as adjustable operating parameters of the medical device in question, like amplitude and width of stimulation pulses, programmed stimulation rate, and diagnostic data, like electrode lead impedance, actual stimulation rate and current consumption of the stimulator electronics, as well as mode of operation of the medical device. This means that the time from RRT till the battery reaches its end of life is also depending on these factors.

Disclosure of the Invention

The purpose of the present invention is to provide an improvement of the previously known technique for determining RRT from measurements of the battery internal impedance, whereby a sufficiently long safety period between RRT and the battery end of life is secured also when factors affecting the current consumption are changed.

This purpose is obtained by a method and a circuit of the kind set forth in the introductory portion of the description and having the characterizing features of claim 1 and claim 9 respectively.

Thus, contrary to the situation in the prior art solutions where one single fixed battery impedance limit is used for determining RRT, a limit value is used in the present invention which is changed in response to changes of operating condition affecting the current consumption. When e.g. settings of the medical device in question are changed or the patient load towards which the device is stimulating is changed, the battery impedance limit value used as an RRT

indicator is adjusted correspondingly. Thus, with a circuit according to the invention RRT is automatically changed when factors affecting the current consumption are changing. In this way there will always be a sufficiently long time between RRT and end of life of the battery.

According to an advantageous embodiment of the method according to the invention said RRT is determined from the result of the comparison of the measured battery internal impedance with a predetermined limit value according to pre-defined worst conditions of operation. Examples of such worst conditions could be e.g. 100% stimulation and e.g. 250 Ohms drop in the lead impedance. By using such a procedure for the RRT determination the safety of the patient is further increased.

According to an advantageous embodiment of the circuit according to the invention the limit value changing means includes a plurality of registers storing different pre-programmed impedance limit values and a pointer for selecting one register of said plurality of registers, which is storing an impedance limit value suitable for use in said comparator means under the actual operating conditions of the heart stimulator. The registers are preferably programmed when the heart stimulator is manufactured. By using such preprogrammed registers patient safety is improved since it eliminates the risk of erroneous programming of this vital parameter.

According to another advantageous embodiment of the circuit according to the invention an indicator is provided to be activated if, in reprogramming the heart stimulator, its operating parameters are changed such that a hazardous increase of the current consumption will result. This is an important safety increasing feature of the circuit according to the invention, since an indication is then immediately given if the heart stimulator is reprogrammed into a mode of operation with an increased current consumption that would result in a quick discharge of the battery.

According to still other advantageous embodiments of the circuit according to the invention the limit value changing means is implemented in an external programmer devised for communication with the heart stimulator by a telemetry link, preferably also the RRT determining means is implemented in such an external programmer. Thus, an external programmer is provided with calculation capacity necessary for determining a suitable impedance limit value and this limit value is then automatically set by the programmer for RRT determination.

Brief Description of the Drawings

To explain the invention more in detail certain embodiments of the invention will now be described with reference to the drawings, on which

figure 1 is a block diagram illustrating schematically a heart stimulator provided with an embodiment of the circuit according to the invention, and

figure 2 is a flow chart illustrating an example of the operation of the circuit according to the invention, and

figures 3a and 3b illustrate the RRT-impedance register 17 and pointer 19 which indicates actual RRT-impedance according to the invention.

Description of Preferred Embodiments

Figure 1 shows schematically in the form of a block diagram a heart stimulator connected through a lead 2 to the heart 4 of a patient. The heart stimulator comprises a battery 6 for supplying necessary electric energy to the stimulator electronics 8 and for charging a discharge capacitor 10 for delivery of stimulation pulses to the heart 4 by the lead 2.

An impedance measurement means 12 is connected to the battery 6 for measuring the internal battery impedance. A comparison means 14 is connected to the impedance measurement means 12 for comparing the measured internal impedance with a predetermined limit value. A determining means 16 is provided for determining RRT from the results of this comparison.

Current measurement means 18, 20 are further provided to continuously measure the current supplied to the stimulator electronics 8 and the current delivered to the discharge capacitor 10 for stimulation pulse delivery.

Various controlling and timing functions of the heart stimulator are performed by a control unit 30. Thus, e.g. charging of the discharge capacitor 10 and delivery of stimulation pulses are controlled from the control unit 30 by schematically shown switches 32 and 34 respectively.

The control unit 30 also includes means 31 for measuring diagnostic data like electrode lead impedance, actual stimulation rate and current consumption of the stimulator electronics.

A limit value changing means 15 is provided to automatically change the limit value of the comparator means 14 in response to changes of operating conditions like measured diagnostic data of the heart stimulator, programmed operating parameters, including mode of operation of the stimulator, etc. This limit value changing means 15 includes a plurality of registers 17 storing different impedance limit values programmed at the manufacture of the device. A pointer 19 is provided to point out one specific register of this plurality of registers 17, which is storing an impedance limit value suitable for use in the comparator means 14 under the actual operating conditions of the heart stimulator. When measured diagnostic data or programmed parameters are changed the pointer 19 automatically points out another register 17 storing a value which is suitable for use for the changed operating condition.

An external programmer 22 is devised for communication with the heart stimulator electronics 8 by a telemetry link 25, 27. By this programmer 22 programmable operating conditions of the heart stimulator can be reprogrammed via the telemetry link 25, 27 and the controlling unit 30. Such a reprogramming

also results in a change of the limit value used in the comparison means 14 by selection of another register 17 by the pointer 19.

Results from the RRT determining means 16 are read by the programmer 22 via the telemetry link 25, 27 as well as other operating data of the stimulator determined and stored in the control unit 30.

If one or more parameters are changed in a reprogramming operation, e.g. the pulse rate is changed such that the current consumption is drastically increased which would result in a quick discharge of the battery, an indicator 21 is activated to draw the physicians attention to this circumstance.

As an alternative the external programmer 22 can include necessary calculating means 23 for determining RRT directly from the result of the comparison performed by the comparison means 14, i.e. the RRT determining means is contained in the programmer 22. This is indicated in figure 1 by the dashed line 24 between the comparison means 14 and the implanted part 27 of the telemetry link for further communication with the external programmer 22.

As an additional safety measure RRT is preferably determined based on a worst case parameter values, e.g. 100% pacing, a resistance drop of the lead impedance of 250 Ohms, together with programmed parameters such as programmed rate, programmed mode of operations of the heart stimulator, etc.

Thus, by choosing between preprogrammed register values and pointing out a suitable value, a sufficient time between RRT and end of life of the battery is always secured based on a worst case calculation, and when a physician makes a reprogramming of the implanted medical device, the limit value for RRT determination is automatically adjusted if necessary.

As an example the heart stimulator illustrated in figure 1 could be a dual chamber pacemaker having five registers 17 preprogrammed with battery impedance limit values.

Before a follow up procedure the pacemaker is programmed according to the following shipped settings: DDD-mode, basic rate 75, pulse amplitude 3,9 V, pulse width 0.5 msec, and RRT battery impedance limit value is set to 13 kOhm, see figure 3a.

During the follow-up the heart stimulator is reprogrammed to VDD-mode with basic rate 45, pulse amplitude 2.4 V, and pulse width 0.25 msec. The electrode lead impedance is measured to 750 Ohm.Based on the information above the register containing 15 kOhm value is determined with the aid of the invention to be used for RRT determination as indicated in fig 3b.

The function of one embodiment of the invention applied to a pacemaker is illustrated by the flow chart of figure 2.

Thus, the telemetry channel is opened and interrogation of the implanted pacemaker is started, block 30. Pacing parameters having impact on RRT determination, e.g. pulse amplitude, pulse width, programmed rate, pacing mode, and if rate response function is activated, etc. are then interrogated, block 32. Also diagnostic data having impact on RRT determination, e.g. lead impedance, actual paced rate (if other than the programmed rate), and electronics' current consumption, are interrogated, block 34. If no such values are stored measurements of necessary values are performed. A RRT limit value is then calculated based on the data retrieved and taking a worst case into account e.g. a lead impedance decrease of 250 Ohm, 100% pacing, 10% of the time at maximum sensor rate or maximum tracking rate depending on the programming of the pacemaker, and also taking a higher measured rate into account if the pacemaker is programmed to a tracking mode, i.e. XDD, block 36.

CLAIMS

1. A method of determining recommended replacement time, RRT, of a battery of an implantable medical device comprising the steps of measuring the battery's internal impedance, comparing said measured impedance with a predetermined limit value, and determining the RRT from the result of this comparison, **characterized in** that said limit value is changed in steps by selecting a limit value among a plurality of predetermined values.

2. The method according to claim 1, **characterized in** that said operating conditions comprise adjustable operating parameters of the medical device.

3. The method according to any one of the preceding claims, **characterized in** that said operating conditions comprise measured diagnostic data of the medical device affecting its current consumption.

4. The method according to any one of the preceding claims, **characterized in** that said operating conditions comprise mode of operation of the medical device.

5. The method according to claim 2, said medical device being a heart stimulator, **characterized in** that said adjustable operating parameters include amplitude and width of stimulation pulses and programmed stimulation rate.

6. The method according to claim 3, said medical device being a heart stimulator, **characterized in** that said diagnostic data include electrode lead impedance, actual stimulation rate and current consumption of the stimulator electronics.

7. The method according to any one of the preceding claims, **characterized in** that said RRT is determined from the result of said comparison according to predefined worst conditions of operation.

8. A circuit for determining recommended replacement time, RRT, of an implantable heart stimulator having a battery, said circuit including an impedance measurement means (12) for measuring the internal impedance of the stimulator battery (6), a comparator means (14) for comparing the measured internal impedance with a predetermined limit value, and a determining means (16, 23) for determining the RRT from the result of this comparison, **characterized in** that said limit value is changed by a limit value changing means (15) which includes a plurality of registers (17) storing different preprogrammed impedance limit values and a pointer (19) for selecting one register of said plurality of registers, which is storing an impedance limit value suitable for use in said comparator means (14) under the actual operating conditions of the heart stimulator.

9. The circuit according to claim 8, **characterized in** that said limit changing means (15) is adapted to receive programmed operating parameters of the heart stimulator and in that said pointer (19) is controlled by this received parameters to select one register of said plurality of registers (17) which is storing a corresponding suitable impedance limit value for use in said comparator means (14).

10. The circuit according to claim 8 or 9, **characterized in** that said limit changing means (15) is adapted to receive measured diagnostic data of the heart stimulator and in that said pointer (19) is controlled by this received data to select one register of said plurality of registers (17) which is storing a corresponding suitable impedance limit value for use in said comparator means (14).

11. The circuit according to any one of the claims 8 – 10, **characterized in** that an indicator (21) is provided to be activated if, in reprogramming the heart stimulator, its operating parameters are changed such that a hazardous increase of the current consumption will result.

12. The circuit according to any one of the claims 8 - 11, **characterized in** that said determining means (23) is implemented in an external programmer (22) devised for communication with the heart stimulator by a telemetry link (25,27).

13. An implantable heart stimulator, characterized by a circuit according to any one of the claims 8 - 12.

Fig. 1

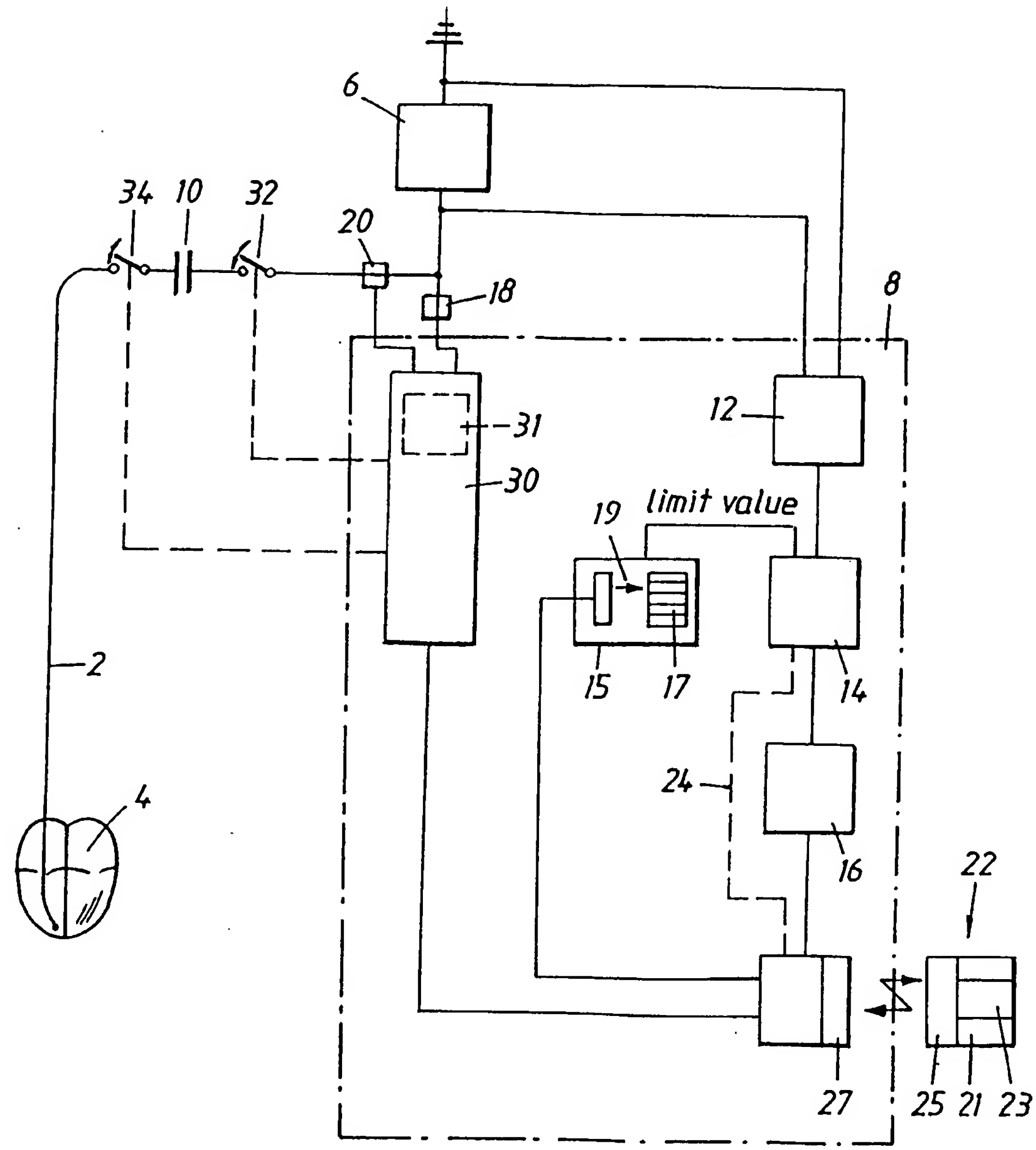


Fig. 3a

11 kOhm	
13 kOhm	<= 19
15 kOhm	
17 kOhm	
19 kOhm	

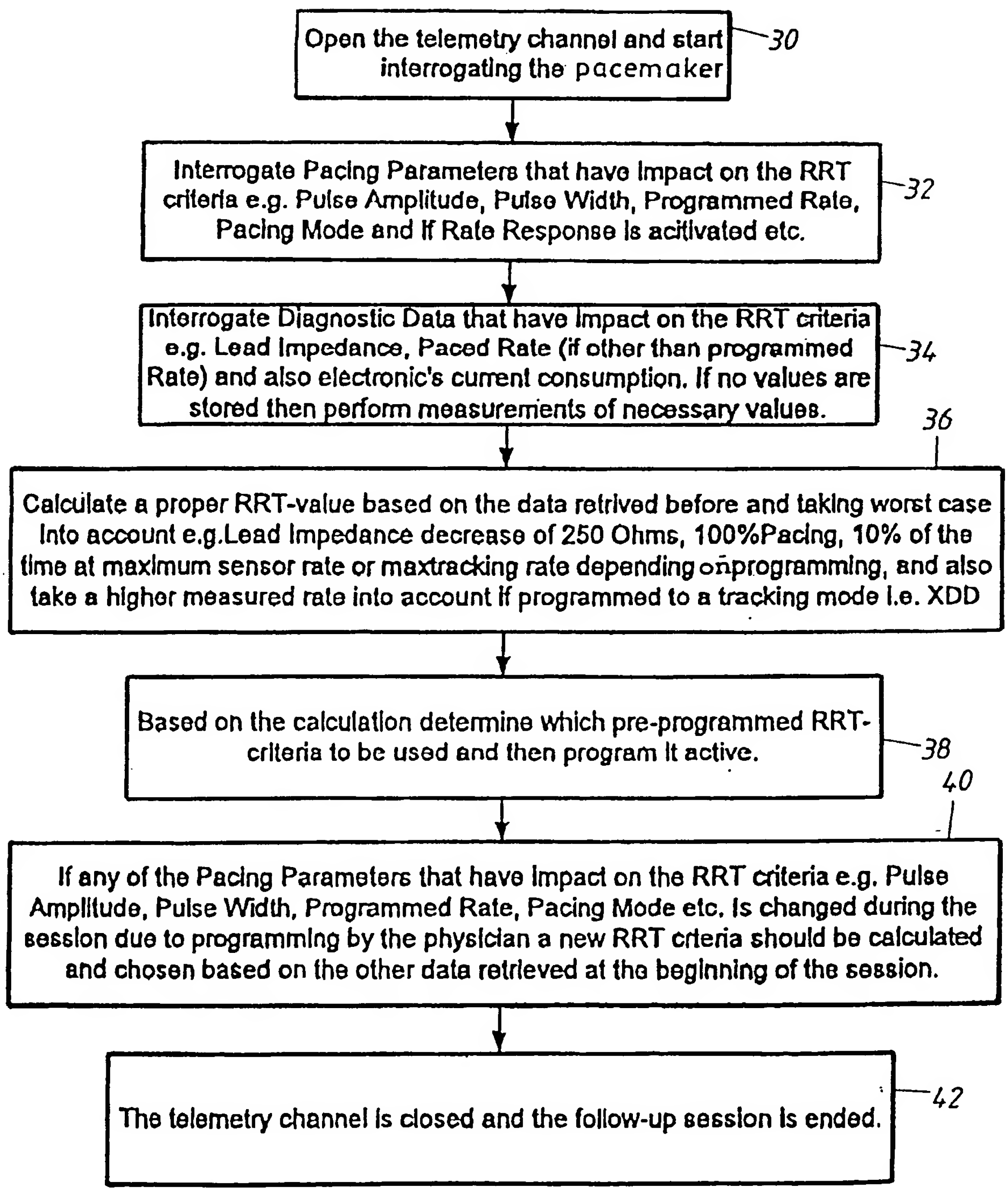
17

Fig. 3b

11 kOhm	
13 kOhm	
15 kOhm	<= 19
17 kOhm	
19 kOhm	

17

Fig. 2


Open the telemetry channel and start interrogating the pacemaker
30
Interrogate Pacing Parameters that have Impact on the RRT criteria e.g. Pulse Amplitude, Pulse Width, Programmed Rate, Pacing Mode and If Rate Response is acitivated etc.
32
Interrogate Diagnostic Data that have Impact on the RRT criteria e.g. Lead Impedance, Paced Rate (if other than programmed Rate) and also electronic's current consumption. If no values are stored then perform measurements of necessary values.
34
36
Calculate a proper RRT-value based on the data retrived before and taking worst case into account e.g.Lead Impedance decrease of 250 Ohms, 100%Pacing, 10% of the time at maximum sensor rate or maxtracking rate depending onprogramming, and also take a higher measured rate into account if programmed to a tracking mode i.e. XDD
Based on the calculation determine which pre-programmed RRT-criteria to be used and then program it active.
38
40
If any of the Pacing Parameters that have Impact on the RRT criteria e.g. Pulse Amplitude, Pulse Width, Programmed Rate, Pacing Mode etc. is changed during the session due to programming by the physician a new RRT crteria should be calculated and chosen based on the other data retrieved at the beginning of the session.
The telemetry channel is closed and the follow-up session is ended.
42

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/01957

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/37, G01R 31/36
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N, G01R

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4290429 A (R. BLASER), 22 Sept 1981 (22.09.81), column 1, line 22 - line 58 --	1-7
A	EP 0058603 A1 (MEDTRONIC, INC.), 25 August 1982 (25.08.82), abstract --	1-13
A	EP 0431437 A2 (SIEMENS ELEMA AB), 12 June 1991 (12.06.91), column 8, line 8 - line 33 --	1-13
A	US 5369364 A (W.C.M. RENIRIE ET AL.), 29 November 1994 (29.11.94), column 3, line 6 - line 16 --	1-13

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 January 2001	18 -01- 2001
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Nikolaj Hautaviita/AE Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 00/01957

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
D,A	US 5769873 A (A.E. ZADEH), 23 June 1998 (23.06.98), abstract --	1-13
D,A	US 4715381 A (L. MOBERG), 29 December 1987 (29.12.87), abstract --	1-13
D,A	US 5741307 A (M.W. KROLL), 21 April 1998 (21.04.98), abstract --	1-13
D,A	US 5370668 A (M.B. SHELTON ET AL.), 6 December 1994 (06.12.94), abstract --	1-13
D,A	US 5800472 A (B.M. MANN), 1 Sept 1998 (01.09.98), abstract -- --------	1-13

INTERNATIONAL SEARCH REPORT Information on patent family members	04/12/00	International application No. PCT/SE 00/01957

Patent document cited in search report			Publication date	Patent family member(s)			Publication date
US	4290429	A	22/09/81	AT	3184	T	15/05/83
				DE	2913399	A	09/10/80
				DE	3062929	D	00/00/00
				EP	0017608	A,B	15/10/80
				SE	0017608	T3	
EP	0058603	A1	25/08/82	SE	0058603	T3	
				AU	547888	B	07/11/85
				AU	8050982	A	26/08/82
				DE	3270708	D	00/00/00
				DE	3280360	A	31/10/91
				EP	0160801	A,B	13/11/85
				SE	0160801	T3	
EP	0431437	A2	12/06/91	AU	619721	B	30/01/92
				AU	6558590	A	13/06/91
				DE	69028900	D,T	20/03/97
				JP	1924153	C	25/04/95
				JP	3186273	A	14/08/91
				JP	6049077	B	29/06/94
				US	5031616	A	16/07/91
				US	5127402	A	07/07/92
				US	5228439	A	20/07/93
US	5369364	A	29/11/94	NONE			
US	5769873	A	23/06/98	NONE			
US	4715381	A	29/12/87	DE	3535202	A	02/04/87
				DE	3666916	D	00/00/00
				EP	0218008	A,B	15/04/87
US	5741307	A	21/04/98	US	5925068	A	20/07/99

INTERNATIONAL SEARCH REPORT
Information on patent family members

04/12/00

International application No.
PCT/SE 00/01957

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5370668 A	06/12/94	AU 676749 B	20/03/97
		AU 686526 B	05/02/98
		AU 687696 B	26/02/98
		AU 1242497 A	27/03/97
		AU 1242597 A	27/03/97
		AU 7093094 A	24/01/95
		CA 2164425 A	12/01/95
		DE 69405869 D,T	30/04/98
		DE 69423918 D,T	03/08/00
		EP 0706407 A,B	17/04/96
		SE 0706407 T3	
		EP 0763747 A,B	19/03/97
		SE 0763747 T3	
		JP 2871097 B	17/03/99
		JP 8508437 T	10/09/96
		US 5402070 A	28/03/95
		WO 9501205 A	12/01/95
US 5800472 A	01/09/98	NONE	

Based on the calculation in block 36 it is determined which preprogrammed RRT-criteria, i.e. which preprogrammed register 17 should be used and it is then programmed into an active state (by pointer 19), block 38. If any of the pacing parameters that have impact on the RRT criteria, e.g. pulse amplitude, pulse width, programmed rate, pacing mode, etc. are changed during the follow-up session due to reprogramming of the pacemaker by the physician, a new RRT-criteria should be calculated and chosen on the basis of these new data, and other unchanged data retrieved at the beginning of the session, block 40. Finally the telemetry channel is closed and the follow-up session is ended, block 42.